DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 6, 2014

Lutronic Corporation
Dr. Jhung Won Vojir
Global Regulatory Officer
6 Neshaminy Interplex, Suite 100
Trevose, Pennsylvania 19053

Re: K141555
Trade/Device Name: ADVANTAGE Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 10, 2014
Received: October 14, 2014

Dear Dr. Jhung Won Vojir:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ADVANTAGE Laser System

Indications for Use:

The ADVANTAGE Laser System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The ADVANTAGE Laser System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

The ADVANTAGE Laser System with D1-800 Handpiece is indicated for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudofolliculitis barbae. The ADVANTAGE Laser System with D1-800 Handpiece is also indicated for hair removal, permanent hair reduction defined as the long-term stable reduction in the number of hairs re-growing after the last treatment measured at 6, 9, and 12 months, and the treatment of benign pigmented lesions and leg veins.

The ADVANTAGE Laser System with D3-800 Handpiece is indicated for hair removal and permanent hair reduction defined as the long-term stable reduction in the number of hairs re-growing after the last treatment measured at 6, 9, and 12 months.

The ADVANTAGE Laser System with D1-1064 Handpiece is intended for treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.
The ADVANTAGE Laser System with D1-1064 Handpiece is intended for hair removal, permanent hair reduction, and the treatment of Pseudofolliculitis Barbae (PFB).
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Prescription Use X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over The Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

The ADVANTAGE Laser System with D1-1064 Handpiece is intended for the treatment of benign pigmented lesions, including age spots, solar lentigines, café-au-lait spots, nevi of Ota/Ito, melasma, Becker's nevi and other benign pigmented lesions.
The ADVANTAGE Laser System with D1-1064 Handpiece is also intended for treatment of wrinkles.

The ADVANTAGE Laser System with D1-1064 Handpiece is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary for the
Lutronic Corporation ADVANTAGE Laser System

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Applicant:	Lutronic Corporation 219, Sowon-ro Deogyang-gu Goyang-si, Gyeonggi-do 410-722 Republic of Korea
Contact Person:	Jhung Won Vojir, Ph.D. Global Regulatory Officer Lutronic, Inc. 6 Neshaminy Interplex, Suite 100 Trevose, PA 19053 Telephone: 215-205-2219 Fax: 609-488-6958 Email: jvojir@lutronic.com
Summary Preparation Date:	June 11, 2014

2. Names

Device Name:	ADVANTAGE Laser System
Classification Name:	Powered laser surgical instrument
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Common/Usual Name:	Pulse Diode Array Laser
Product Code:	GEX
Regulation No.:	878.4810
Class:	II
Panel Identification:	General & Plastic Surgery

3. Predicate Devices

Lutronic Corporation ADVANTAGE Laser System, cleared in 510(k) K113502 and the Lumenis Ltd. ET LighSheer 1060, cleared in 510(k) K133319.

4. Device Description

The ADVANTAGE Laser System with D1-1064 Handpiece is a treatment handpiece, intended to be used with ADVANTAGE Laser System 510(k) cleared in K113502 on April 5, 2012. The ADVANTAGE Laser System with D1-1064 Handpiece delivers laser energy through a 10 x 10 mm tip with a fluence of up to 100 J/cm^2. The settings for this handpiece are pulse duration from 5-400 msec, and a pulse repetition rate up to 3 Hz maximum. The ADVANTAGE Laser System with D1-1064 Handpiece is water-cooled to provide active skin cooling.

5. Indications for Use

The ADVANTAGE Laser System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The ADVANTAGE Laser System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

The ADVANTAGE Laser System with D1-800 Handpiece is indicated for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudofolliculitis barbae. The ADVANTAGE Laser System with D1-800 Handpiece is also indicated for hair removal, permanent hair reduction defined as the long-term stable reduction in the number of hairs re-growing after the last treatment measured at 6, 9, and 12 months, and the treatment of benign pigmented lesions and leg veins.

The ADVANTAGE Laser System with the D3-800 Handpiece is indicated for hair removal and permanent hair reduction defined as the long-term stable reduction in the number of hairs re-growing after the last treatment measured at 6, 9, and 12 months.

The ADVANTAGE Laser System with D1-1064 Handpiece is intended for treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.
The ADVANTAGE Laser System with D1-1064 Handpiece is intended for hair removal, permanent hair reduction, and the treatment of Pseudofolliculitis Barbae (PFB). Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.
The ADVANTAGE Laser System with D1-1064 Handpiece is intended for the treatment of benign pigmented lesions, including age spots, solar lentigines, café-au-lait spots, nevi of Ota/Ito, melasma, Becker's nevi and other benign pigmented lesions.
The ADVANTAGE Laser System with D1-1064 Handpiece is also intended for treatment of wrinkles.
The ADVANTAGE Laser System with D1-1064 Handpiece is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

6. Substantial Equivalence

The ADVANTAGE Laser System with D1-800 Handpiece and D3-800 Handpiece is substantially equivalent to the previously cleared ADAVANTAGE Laser System, cleared in 510(k) K113502. The ADVANTAGE Laser System with D1-800 handpiece and the D3-800 handpiece has the same intended use as the predicate device.
The ADVANTAGE Laser System with D1-1064 Handpiece has the same principles of use and mechanisms of operation as Lutronic Corporation treatment handpieces cleared in 510(k) K113502, and has equivalent performance characteristics. The materials used for ADVANTAGE Laser System with D1-1064 nm and the manufacturing methods are identical to the devices cleared in 510(k) K113502. The difference resides in the wavelength of 1064 nm for the proposed device in comparison with 805 nm for the cleared treatment handpieces.
The ADVANTAGE Laser System with D1-1064 Handpiece has the same intended use and have equivalent performance characteristics as the Lumenis Ltd. ET LightSheer cleared in 510(k) K13319.

7. Performance Data

None presented.